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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,839	03/07/2001	Toshihiro Shimizu	2535US1P	7614

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TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
475 HALF DAY ROAD
SUITE 500
LINCOLNSHIRE, IL 60069

EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/800,839	Applicant(s) Shimizu et al.
	Examiner Susan T. Tran	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 8, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-7 and 9-20* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-7 and 9-20* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment A filed 03/07/01, Information Disclosure Statement filed 03/07/01, 01/15/02, and 08/08/02, Request for Extension of Time filed 01/15/02, Declaration under 37 CFR§1.132 filed 01/15/02, Amendment B filed 01/15/02, and Request for Continued Examination filed 08/08/02.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/08/02 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,299,904 ('904). Although the conflicting claims are not identical, they are not patentably distinct from each other because '904 claims a buccal disintegration tablet comprising candesartan cilexetil, sugar, and low-substituted hydroxypropylcellulose (7% to 9.9%). Therefore, those of ordinary skill would expect a similar buccal disintegration formulation from the use of the instant invention given the claims of '904. Although the hydroxypropoxyl group of '904 is from 7% to 9.9%, the claimed invention does not state how much less than 7%. There are no unusual and/or unexpected results which would rebut prima facie obviousness.

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al. US 5,958,453

Ohno teaches a solid pharmaceutical composition in powder or granular that can be made into tablet suitable for buccal administration (column 2, lines 13-61). The composition comprising active ingredient; sugar, e.g., mannitol or erythritol; and disintegrant, e.g., low substituted hydroxypropyl cellulose at about 1-15 parts by weight base on 100 parts by weight of the solid composition (columns 2 and 5). The active ingredient can be selected from various classes that is disclosed in columns 3-4. Column 6, lines 59-67 further teaches the dissolution of the tablet, which can be completely dissolved in about 0.1 to 1.0 minute.

Although Ohno is silent as to the teaching of the degree substituted of the hydroxypropyl group, Ohno recognizes the advantages result in obtaining buccal tablet having dissolution time within the claimed range. Therefore, it would have been prima facie obvious for one of ordinary skill in the art to, by routine experimentation select a suitable low-substituted hydroxypropyl cellulose to obtain a rapid disintegrate buccal tablet. The expected result would be a buccal

dissolution dosage that has long shelf-life, low toxicity, ease of administration even without water, and having fast disintegration in the oral cavity even without water (column 7, lines 3-25).

5. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al., in view of Shimizu et al. US 6,299,904 (the examiner relies on the priority date of this reference; until the translation of the JP 9-136724 is provided, the patentability will be reconsidered). .

Ohno is relied upon for the reason stated above. Ohno is silent as to the teaching of the claimed active ingredients.

Shimizu teaches buccal disintegration tablet comprising active agents, e.g., manidipine HCl, pioglitazone HCl, candesartan cilexetil, and voglibose. Thus, it would have been prima facie obvious for one of the ordinary skill in the art to modify Ohno's formulation using the active ingredients in view of the teaching of Shimizu. The reason for this modification is to obtain a pharmaceutical preparation having the above active ingredients for oral administration. The unexpected result would be a fast disintegrating tablet with improved disintegrability and/or dissolubility useful for buccal administration.

6. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al., and Shashoua et al. US 5,795,909.

Although Ohno teaches variety of active agents useful for the gastrointestinal function, Ohno is silent as to the specific active agent claimed by the applicant, e.g., lansoprazole.

Shashoua teaches pharmaceutical composition in tablet form comprising active ingredients, e.g., pioglitazone, candesartan, manidipine, and lansoprazole (column 35, lines 4-10). Thus, it would have been obvious for one of ordinary skill in the art to modify Ohno's formulation using the active agents in view of the teaching of Shashoua. The reason for this modification is to obtain a buccal disintegrable solid dosage useful for the treatment of the digestive diseases. The expected result would be a storage stable quick dissolve buccal formulation that can be safely administered orally without water.

Response to Arguments

7. Applicant's arguments filed 08/08/02 have been fully considered but they are not persuasive.

Applicant argues that the cited references do not teach the buccal formulation has no roughness and improved chalky taste. However, it is the position of the examiner that the improved chalky taste and no roughness forming do not support the patentability of subject matter encompassed by the prior art since the prior teaches the use of the same ingredients to obtain the same results desired by the applicant, *e.g.*, tablet having excellent hardness that is completely dissolved within the ranges of about 6 seconds to 60 seconds

Applicant argues that there's no motivation to combine Shashoua and Ohno. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the

teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Shashoua is relied upon solely for the teaching of active ingredient, e.g., lansoprazole, pioglitazone, candesartan, and manidipine in an oral dosage form selected from capsules, tablets, sachets, and lozenges (column 49, lines 28-44).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600